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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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	Application No.	Applicant(s)		
	10/613,842	ANDERSON ET AL.		
Office Action Summary	Examiner	Art Unit		
	SUSAN SU	3761		
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
1) ☐ Responsive to communication(s) filed on 11 A 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This 3) ☐ Since this application is in condition for alloware closed in accordance with the practice under B	s action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) 1-20,22-29,31-33 and 35-42 is/are per 4a) Of the above claim(s) 33 and 35-42 is/are per 5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-20,22-29, 31, & 32 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or are subjected to by the Examine.	withdrawn from consideration. or election requirement. er.			
10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	drawing(s) be held in abeyance. See tion is required if the drawing(s) is ob	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	ate		

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#### **DETAILED ACTION**

#### Status of Claims

Claims 1-20, 22-29, 31-33, and 35-42 are pending, of which Claims 33 and 35-42 are withdrawn and Claims 1, 20, 28, 29, 31, & 32 are amended. New matter is found.

### Response to Arguments

- 1. Applicant's arguments filed 11 August 2010 with respect to the rejection(s) of claim(s) 1, 2, & 4-6 under 35 USC 103 for being obvious over Beverly in view of Kerssies have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Beverly alone.
- 2. Applicant's arguments regarding Beverly's lack of teaching of providing information to the subject have been fully considered but they are not persuasive. Applicant argues that Beverly's device teaches a head-up display that provides the operator instructions for moving the device to align with the subject's eyes, thus it fails to suggest or teach that the device provides information to the subject. However, since the operator is fully capable and has the option to tell the subject to move his/her eyes, the Beverly device is still held to be capable of performing the recited function.
- 3. Applicant's arguments with respect to claims rejected under 35 USC 102 for being anticipated by Kerssies have been considered but are moot in view of the new ground(s) of rejection necessitated by the new amendments.

35 USC § 112, 6th Paragraph

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4. With regard to Applicant's "means for detecting...; means for receiving information...; and means for dispensing..." and "means for capturing an image...; processing means for detecting the position of the eye...", the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for;"
- (B) the "means for" or "step for" must be modified by functional language; and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

- (A) performs the function specified in the claim,
- (B) is not excluded by any explicit definition provided in the specification for an equivalent, and
- (C) is an equivalent of the means- (or step-) plus-function limitation, then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation. See MPEP 2183.

Regarding claims 28 & 29, Applicant appears to have met the requirements set forth in MPEP §2181. However, Examiner finds no further limitations in the specification.

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Regarding claims 31 & 32, Applicant appears to not meet the requirements set forth in MPEP §2181, because the third requirement for invoking 35 USC 112, 6<sup>th</sup> paragraph has not been met.

### Specification

5. The disclosure is objected to because of the following informalities:

In Claims 28 & 29, claim elements "means for detecting...; means for receiving information...; and means for dispensing..." and "means for capturing an image of the eye" are means (or step) plus function limitations that invoke 35 U.S.C. 112, sixth paragraph. The written description only implicitly or inherently sets forth the corresponding structure, material, or acts that perform the claimed functions.

Pursuant to 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181, applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it **expressly recites** the corresponding structure, material, or acts that perform the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or
- (c) **State on the record** what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function.

In the instant case, Examiner considers any detector an equivalent of "means for detecting the position of the eye," any computer/processor to be the equivalent of "means for receiving feedback information," any nozzle or outlet to be "means for dispensing," and any camera to be an equivalent to the "means for capturing an image of the eye" disclosed by applicant, since it performs the same function of

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capturing/obtaining an image of the eye in the same way as the claimed function, with the same result as the device disclosed by Applicant. See MPEP 2183.

### Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 7. Claims 28, 29, 31, & 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 28 has been amended to recite "means for receiving feedback information" but it is noted that Applicant does not teach any means/device that receives *feedback* information since the feedback information is directed to the subject. Additionally, as required by the current claim language, the "means for receiving feedback information" would also provide feedback information to the subject. It is noted that a means/device that performs both functions, namely receiving <u>and</u> providing feedback information, is not taught in the original disclosure of the instant Application.
- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 31 & 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim limitation "means for receiving feedback information" and "means for dispensing" uses the phrase "means for" or "step for", but it is modified by some structure, material, or acts recited in the claim. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph.

If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that the phrase "means for" or "step for" is clearly **not** modified by sufficient structure, material, or acts for performing the claimed function.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that it will clearly not be a means (or step) plus function limitation (*e.g.*, deleting the phrase "means for" or "step for").

## Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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11. Claims 1, 4-6, 8, 16, 20, & 23 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Beverly (US 6,945,650).

With regard to Claims 1 & 2, Beverly teaches an ophthalmic apparatus comprising:

an eye-positioning device comprising:

an electronic feedback device (24); and

an applicator (exit of 12) for dispensing the fluid into the eye conditionally upon positioning of the eye in the desired position; and

an eye position detector (42A & 42B) for detecting the position of the eye.

The language "configured to provide information to a subject who is moving an eye from a current position to a desired position relative to the eye positioning device" is functional language. While features of an apparatus may be recited either structurally or functionally, claims directed to a device must be distinguished from the prior art in terms of structure rather than function, because device claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. In the instant case, Beverly provides positioning information to the operator, who then is capable and free to instruct the subject to move his/her eyes to

the desired position. Beverly's device is capable of performing the recited function in its normal operation and thus anticipates the claim.

With regard to Claim 4, Beverly also teaches that the feedback device provides visual cues (Col. 8 lines 35-37).

With regard to Claim 5, Beverly also teaches a display (24) for displaying a real-time image of the eye and a target (as outlined by polar array 82), such that when the eye is aligned with the target, the eye is in the desired position.

With regard to Claim 6, Beverly also teaches a processor (60) and an image pick-up device (inherent since an image of the eye is provided on display 24) for capturing an image of the eye. The claim language "for processing the image of the eye and determining whether the eye is in the desired position for administering the fluid to the eye" is considered to be intended use of the processor. Since the prior art invention substantially meets the structure of the current device as claimed, it is capable of performing the intended use and therefore meets the claim.

With regard to Claim 8, Beverly also teaches feedback signals (such as polar array 82 and LED array 90 presented on display 24 that indicate if the pupil/iris is positioned correctly), the feedback signals corresponding to directions for moving the eye to the desired position.

With regard to Claim 16, Beverly also teaches a fluid reservoir (12, wherein the tube is at least momentarily a storage space for the fluid immediately prior to its discharging) for storing the fluid and delivering the fluid to the fluid dispenser.

With regard to Claim 20, Beverly teaches an ophthalmic apparatus, comprising:

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a dispensing apparatus (exit of 12) for dispensing fluid into an eye of a subject;

an eye-position detector (42A & 42B) for detecting the current position of the eye relative to the dispensing apparatus;

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a feedback device for receiving information from the eye-position detector corresponding to the position of the eye.

The language "wherein the feedback device provides feedback information to the subject that assists the subject in moving the eye from the current position to a predetermined position relative to the dispensing apparatus for administering the fluid to the eye" is functional. In the instant case, Beverly provides positioning information to the operator, who then is capable and free to instruct the subject to move his/her eyes to the desired position. Beverly's device is capable of performing the recited function in its normal operation and thus anticipates the claim.

With regard to Claim 23, Beverly also teaches a processor (60) and an image pick-up device (inherent since an image of the eye is provided on display 24) for capturing an image of the eye. The claim language "for processing the image of the eye and determining whether the eye is in the desired position for administering the fluid to the eye" is considered to be intended use of the processor. Since the prior art invention substantially meets the structure of the current device as claimed, it is capable of performing the intended use and therefore meets the claim.

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### Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 13. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 15. Claims 3 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly as applied to Claim 1 above, and further in view of Yee (US 6,270,467).

  Beverly does not teach an audible cue. Yee teaches an ophthalmic apparatus providing

audible cues (30). Yee also teaches a user interface (5, 68) that can be programmed to set the operating parameters of the apparatus and a graphical interface element (6, 70). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Yee for the purpose of lending a user assistance to align his/her eyes for the subsequent medical procedure and for making the device more user-friendly.

- 16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly in view of Miwa (US 6,299,305). Beverly does not expressly teach a CCD camera. Miwa teaches an ophthalmic apparatus that uses a CCD camera (10). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Miwa for the purpose of using a standard technology for capturing the position of the eye.
- 17. Claim 9-10, 14-15, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverley in view of Vo.

With regard ton Claims 9-10 & 22, Beverly does not teach a spectacle frame. Vo teaches a spectacle-style applicator with a fluid dispenser (400 & 500) supported by the frame. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Vo for the purpose of adapting the alignment apparatus of Beverly to be more portable and for more comfortable wear.

With regard to Claims 14-15, Beverly does not teach a controller for actuating the fluid dispenser to dispense a predetermined dosage. Vo also teaches a controller (Col. 9 lines 15-16) that actuates the fluid dispenser to dispense a predetermined dosage of

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fluid (Col. 4 lines 29-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Vo for the purpose of having better control over the amount of fluid dispensed into the eye.

- 18. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly and Vo as applied to Claim 9 above, and further in view of Bertera (US 5,368,582). Beverly and Vo do not teach a jet dispenser. Bertera teaches a spectacle-like device with a thermal or piezoelectric jet dispenser (14) with a plurality of orifices to apply treating fluid into an eye (Col. 5 lines 1-12, Col. 9 lines 3-17, Fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly and Vo for the purpose of utilizing a known and practiced technology for dispensing a dosage of treating fluid to the eye.
- 19. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beverley as applied to Claim 1 above, and further in view of Bertera (US 5,368,582). Beverly does not teach a jet dispenser. Bertera teaches a device with a thermal or piezoelectric jet dispenser (14) with a plurality of orifices to apply treating fluid into an eye (Col. 5 lines 1-12, Col. 9 lines 3-17, Fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Bertera for the purpose of utilizing a known and practiced technology for dispensing a dosage of treating fluid to the eye.
- 20. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly as applied to Claim 23 above, and further in view of Wickham et al. (US 6,159,186, "Wickham"). Beverly does not teach that the image capture device is a

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digital camera. Wickham teaches a fluid delivery system that employs a digital camera (28) as an image uptake device, and an image processor (34) capable of processing that camera's images (Col. 2 line 66 to Col. 3 line 13). Beverly's processor is also capable of detecting the position of the eye relative to the predetermined position based on the information from the eye-detectors. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Wickham for the purpose of utilizing a known technology to better determine the eye position.

21. Claims 26 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly and Wickham as applied to Claim 25 above, and further in view of Vo. Beverly and Wickham do not teach a controller for controlling the fluid dispenser. Vo teaches a controller (Col. 9 lines 15-16) that controls a fluid dispenser. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Wickham and Vo for the purpose of utilizing a known technology to better determine the eye position and to have better control over how and when the fluid is dispensed. It would also be obvious to combine the processor of Wickham and the controller of Vo into one single processing unit for the purpose of making it possible to make the processing unit more compact.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 9:00AM-5:00PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/ Examiner, Art Unit 3761 /Tatyana Zalukaeva/ Supervisory Patent Examiner, Art Unit 3761